# EXHIBIT "III"

### **INTRODUCTION TO CASE REVIEW**

As an introduction to the OPMC review of the following physicians' care as it pertains to patients with the diagnosis of Lyme disease, I feel it is important to provide a brief summary of the clinical features of this infectious disease and include the diagnostic criteria that are considered the standard of care in the medical community. In addition, it is also important to review a basic tenet of medical care, that is, the establishment of a differential diagnosis as the foundation to achieving the most accurate and appropriate diagnosis of an individual patient complaint(s) and condition.

### I. LYME DISEASE

Lyme disease is tick-borne infection caused by a spirochete bacteria, Borrelia burdorferi. It is endemic in the northeastern US, and is seen in portions of the upper Midwest and California. As an infectious disease, it has a number of recognizable clinical presentations that serve as the basis for a clinician's diagnosis. Interestingly, many of these clinical features parallel those of a closely related infection caused by another related spirochete, namely syphilis.

Early localized disease is characterized by the appearance of the characteristic skin lesion, erythema migrans (EM), with or without constitutional symptoms. EM usually occurs within one month following the tick bite.

Early disseminated disease is characterized by multiple erythema migrans lesions (that typically occur days to weeks after infection) and/or neurologic and/or cardiac findings (that typically occur weeks to months after infection). Some of these patients have no history of antecedent early localized Lyme disease.

Late Lyme disease is typically associated with intermittent or persistent arthritis involving one or a few large joints, especially the knee (sometimes preceded by migratory arthralgias); and/or certain rare neurologic problems, primarily a subtle encephalopathy or polyneuropathy. Late Lyme disease may develop months to a few years

after the initial infection, and arthritis may be the presenting manifestation of the disease.

Because a definitive diagnosis of Lyme disease can not be made through the isolation and identification of the Borrelia burgdorferi bacteria itself in the laboratory, clinicians are often dependent on supportive antibody testing of the patient's blood in the form of both screening tests (ELISA) and more specific, confirmatory tests (Western Blot). These supportive antibody (serologic) tests can help a clinician confirm their suspicion of Lyme disease after an accurate history taking and full physical examination.

In the cases of untreated, late Lyme disease with either arthritic or neurologic findings, positive serologic testing is virtually universal. Therefore, sequential negative Lyme antibody testing in patients with these complaints should raise considerable concern for an alternative diagnosis other than Lyme disease.

Serologic testing should not be used as tools to screen populations without evidence of clinical disease for possible exposure to Lyme disease, or in the absence of the features of disseminated or late disease. That is, the antibody/serologic testing is only as helpful as the clinical presentation predicts.

As a caveat to serologic testing, positive results often remain positive for years after appropriate antibiotic treatment for Lyme disease, leading to a lack of utility and discrimination of antibody testing in future clinical settings.

The following is a summary of the CDC (Centers for Disease Control) criteria for the definition and features of Late Lyme disease:

The late manifestations include any of the following when an alternate explanation is not found:

### Musculoskeletal system

Recurrent brief attacks of objective joint swelling in one or a few joints, **sometimes** followed by chronic arthritis in one or a few joints. Manifestations not considered as criteria for diagnosis include chronic progressive arthritis not preceded by brief attacks and chronic symmetrical polyarthritis. Additionally, arthralgias, myalgias, or fibromyalgia syndromes alone are **not accepted** as criteria for musculoskeletal involvement.

#### **Nervous system**

Lymphocytic meningitis, cranial neuritis, particularly facial palsy (may be bilateral), radiculoneuropathy or, rarely, encephalomyelitis alone or in combination. Encephalomyelitis must be confirmed by showing antibody production against B. burgdorferi in the cerebrospinal fluid (CSF), which is demonstrated by a higher titer of antibody in CSF than in serum. Headache, fatigue, paresthesias, or mild stiff neck alone are **not accepted** as criteria for neurologic involvement.

#### Cardiovascular

Acute onset, high grade (2nd or 3rd degree) atrioventricular conduction defects that resolve in days to weeks and are sometime associated with myocarditis. Palpitations, bradycardia, bundle branch block, or myocarditis alone are not accepted as criteria for cardiovascular involvement

# II . THE DIFFERENTIAL DIAGNOSIS IN MEDICAL DECISION MAKING

The basis for approaching a medical and/or surgical diagnosis is the establishment of a differential diagnosis. This tool enables the clinician to assemble all of the patient's subjective complaints, physical examination findings, and laboratory/radiologic data into a comprehensive and logical list of reasonably potential diagnoses. This list is at first broad, but meant to allow the clinician to focus on a sensible approach to make the most rapid and accurate diagnosis. Failure to be inclusive of all possible diseases, and reach a conclusion without all appropriate potentials excluded, may lead to an incorrect

diagnosis and prohibit a patient from receiving prompt, effective therapy. In addition, making an <u>exclusive</u> medical diagnosis without the requisite supportive diagnostic testing is not only faulty, but would disregard other potential real illnesses, or mistakenly ignore that a patient's symptoms may in fact be psycho-somatic, and not due to a true medical condition.

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I have reviewed all of the records regarding the care of Maria Vele by Dr. D. Care of from 2/19/08 until 5/5/08. Included in these records were the prior office notes and laboratory results of Dr. Element

### **Medical Summary**

M v was seen in Dr. Call office on just two occasions, on 2/19/08 and again on 3/18/08.

At the initial visit, Ms. Vaccompleted a review of systems scale (ranging from none to severe) describing her subjective complaints for thirty (30) different symptoms.

History obtained included her recent termination of pregnancy in 10/07 and diverticulitis in 11/07. Also, it is written that the patient had "Lyme disease -positive" three weeks prior under the care of Dr. Electric (there is no review of the test report, and "equivocal" result)

A cursory physical exam was documented that did not include vital signs, no record of any examination of the abdomen or musculo-skeletal (joints) system.

Dr. Carried discussed at length the diagnosis of Lyme disease and changes antibiotic therapy from amoxicillin to doxycycline 300 mg per day for a month.

On 3/18, Ms. V returns to Dr. C office with "gains" described by the examiner. The physician's impression is that the patient continues to suffer from Lyme disease, with mild gains. Treatment continues with doxycycline at 300mg/day with consideration given to IV therapy if symptoms persist. M V has no further visits with Dr. C only telephone communication with his office to inform that patient is seeing another physician, Dr. k who told her that she never had Lyme disease based upon further testing.

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## EVALUATION OF PERFORMANCE OF DEC. C. M.D. IN

- 1. In terms of the diagnosis and treatment of Lyme disease in the case of M. V. Dr. Office of fails to meet the minimum fails to meet the minimum standards for the treatment of this infectious disease. There is no eliciting of a history to suggest exposure to Lyme disease, no formal joint examination performed to investigate Lyme arthritis, and no acknowledgement of the fact that the basis for Dr. recent diagnosis was solely based on an equivocal Lyme antibody screening test. No confirmatory testing is ever discussed or order<u>ed by D</u>r. C In addition, the consideration raised to intensify therapy with intravenous antibiotics based upon the lack of any consistent history, physical examination findings, or confirmatory Lyme testing fails on all accounts to meet the minimum standards expected of a family practitioner, internist, or infectious diseases specialist for the care of a patient with Lyme disease.
- 2. As far the general medical care of Mark V., Dr. Cexhibited a severe deviation from the standard of care. While eliciting a history of sequential pelvic and intra-abdominal infections during the period between 10/07 and 12/07 during Ms. Visit initial visit on 2/19/08, and acknowledging abnormal liver function tests and an elevated sedimentation rate, he fails to construct a basic differential diagnosis to include a potential ongoing, or remitting infectious disorder

By adhering strictly to the diagnosis and treatment of Lyme disease despite the lack of any physical findings and/or laboratory evidence, Dr. Communication into Ms. active medical problems. The minimal standards expected of a

physician in this case would be to consider CT scanning of the abdomen and pelvis and additional blood testing to follow up recent laboratory abnormalities.

### 2. CASE OF E

At no place in the record is there a result of this Lyme test, yet on all subsequent visits "Lyme" is included as the patients diagnosis, along with phlebitis. Additional antibiotics are prescribed for four and a half (4.5) more months. On follow-up office visits "Lyme" is crossed out and

"Cellulitis" is inserted as the medical problem regarding his chronic right leg findings of skin discoloration. In the medical record, Dr. Calling that the cellulitis "mimics" Lyme, and his findings are supported by a surgeon ( no record of this consultation).

Despite the lack of any history of tick exposure, or clinical symptoms of Lyme, repeated Lyme testing continues for this patient through **2006.** None of these serologic tests are supportive of the diagnosis of Lyme disease. The patient is prescribed multiple courses of antibiotics from 2000 through 2007 (approximately 18 months of therapy over this period).

The medical record repeatedly reports various levels of "gain", "steady gain" of Lyme disease symptoms that consist of fatigue and the chronic venous stasis/post-phlebitis skin changes of Mr. keeping right lower leg.

## EVALUATION OF PERFORMANCE BY DECEMBRICATION OF PERFORMANCE BY DESCRIPTION OF MICH. M.D. IN

- 1. Dr. C exhibited a severe deviation from the standard of care in the diagnosis and treatment of Lyme disease in this case. The melding of two distinct clinical diagnoses, those of chronic venous stasis dermatitis/phlebitis/cellulitis with Lyme disease is not an accepted standard. There is in fact no clinical entity described in the medical literature of "Lyme Mimicry", that would be confused with the skin changes of the disorders mentioned above. This diagnosis is a fabrication, and Dr. C seeking confirmation of this purported infectious disease anomaly from a surgeon would not meet the acceptable standards for diagnosis of Lyme disease by an internist, family practitioner, or infectious disease specialist.
- 2. The continuation of repeated, prolonged antibiotic courses and the ordering of multiple Lyme tests in order to justify this therapy, in a patient without any clinical stigmata of this disease, is an additional severe deviation from the accepted standard of care.

### 3. CASE OF I

I have reviewed the medical records of I Have Band the care provided by Daniel Care M.D. between 10/10/1997 and 12/28/2004.

### **Medical Summary**

Harmonian was a 49 year old woman at the time of her first evaluation by Dr. Common on 10/10/97. She presented with a history of multiple tick bites in the past, most recently in 8/97, dizziness, problems with concentration and memory, and multiple joint pains. She had been seen by a neurologist previously and had a normal MRI of the brain. Her initial physical examination in Dr. Common office did not include any neurologic or joint exam. A Lyme antibody test in ordered, and prior to results, she was started on doxycycline antibiotic therapy for one month.

The Lyme test is completely negative, and six additional Lyme tests over the next five (5) years are all completely negative. She is given a diagnosis of "sero-negative Lyme" which is carried throughout Dr. medical record.

On 12/1/98, Ms. Harmonis evaluated by a neurologist, Dr. Comparison of the property of comparison of the possibility of cerebral infectious/ inflammatory disease, including multiple sclerosis. A spinal tap is recommended for diagnosis including that of Lyme disease, but the patient refuses. During subsequent visit to Dr. Comparison of the possibility of cerebral infectious/ inflammatory disease, including multiple sclerosis. A spinal tap is recommended for diagnosis including that of Lyme disease, but the patient refuses. During subsequent visit to Dr. Comparison of the patient refuses of the patient refuses.

Because of limited improvement of her neurologic and joint complaints while on oral antiblotic therapy for one year's duration, Dr. Calculated escalates therapy to weekly intra-muscular penicillin injections that continue unabated for 22 months. At the time of the introduction of the penicillin injections, Dr. Calculated discussed using intravenous ceftriaxone but deferred because of her status as " sero-negative Lyme disease".

In total, the patient received antibiotic therapy for a total of three years and eight months.

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Throughout her repeated visits to Dr. Common over this three year and eight month period, there are only four limited physical examinations documented in the patient's record. No exam is performed during the nearly two years of weekly encounters for intra-muscular injections of penicillin. At no time is a formal neurologic or joint examination ever performed, despite her ongoing symptoms which are diagnosed, and treated as sero-negative Lyme disease.

# EVALUATION OF PERFOMANCE OF D. THE CASE OF I H. H.

- 1. During his prolonged care of I have a process of the standard of care in both the diagnosis and treatment of Lyme disease. These are the significant deviations from care:
  - Multiple patient complaints are not followed up with the most basic of physical examinations over three-plus years of treatment.
  - Five years of consecutive negative Lyme antibody tests are documented in the patient record, yet a diagnosis of Lyme disease is the basis for uninterrupted antibiotic therapy.
  - Spinal fluid analysis for the purpose of diagnosing Lyme disease, or other inflammatory central nervous system diseases is not recommended by Dr. C
  - 3. From a standpoint of antibiotic therapy, Dr. Of deviates from all Lyme treatment guidelines with three years and eight months of therapy even if this was a case of an individual with clinical stigmata of Lyme disease, documented by physical findings and supported by positive Lyme antibody testing. In the case of neither clinical or serologic evidence would support any diagnosis of Lyme disease.

### 5. CASE OF D

I reviewed all of the medical records provided in the case of E from 10/15/98 until 3/7/08.

### **Medical Summary**

Description of General Was a 38 year old woman, working as a legal secretary, at the time of her initial evaluation by Dr. Central. She came with complaints of severe fatigue, disturbed sleep, irritability, joint pains, frequent sore throats, nausea and diarrhea. Nine years earlier in 1987 she recalled a bug bite with a small area of redness. One year later a

less than one-inch rash appeared on her thigh, not at the site of the bite. There were no additional symptoms described by the patient to suggest acute or disseminated Lyme disease. In 1990, she sought medical care by another physician for joint pains and was told she had a "borderline" Lyme test and was treated with oral amoxicillin for six (6) weeks. A confirmatory Lyme Western Blot test was negative.

Between 1993 and 1998 she had frequent episodes of fatigue and was diagnosed with Chronic Fatigue Syndrome by another treating physician.

At her first visit with Dr. Common on 10/15/98, she was examined by a nurse practitioner, and diagnosed by Dr. Common with "sero-borderline" Lyme disease without any further laboratory test results. No neurologic or musculoskeletal examination is performed at this initial office visit. Oral antibiotic therapy (cefuroxime) was initiated.

On follow-up visit, Dr. Carrier, who did not examine the patient, makes a diagnosis of neurologic-rheumatologic Lyme disease and recommends continued therapy. No Lyme test has yet been obtained.

Based on ongoing vague neurologic complaints, the patient is seen by a neurologist in 12/98, an MRI is obtained which is clearly abnormal with concern for a demyelinating disease or vasculitis. The neurologist recommends a lumbar puncture for further diagnosis, but this is not done.

Oral antiblotic therapy with cefuroxime is continued for the ensuing five (5) months, despite the patients recurrent complaints of diarrhea. No investigation into antibiotic-associated infectious diarrhea (Clostridium difficile) is pursued by Dr.C. office.

In 3/99, weekly intramuscular penicillin is initiated and continues for five (5) months.

In 6/99, the patient undergoes a SPECT scan of the brain which is reported as abnormal, and no lumbar puncture is considered.

In 7/99, intravenous antibiotic therapy (ceftriaxone) is initiated, and her diarrhea worsens, still without investigation. After three (3) months of intravenous therapy, Dr. returns to weekly intramuscular penicillin injections, that continue for two additional years.

On 11/13/99, the patient complains of a stiff neck and aphasia, and states that her overall symptoms worsen in the warmer weather (re: multiple sclerosis). It is not until 1/4/2002 that the patient has a physical examination in Dr. Complete of the first since 10/15/98. She was never examined by Dr. Complete of the nine years she came to his office.

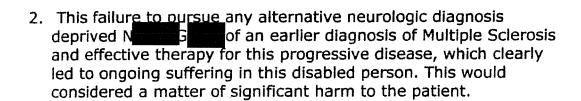
In total, the patient is treated with antibiotics for 38 consecutive months until 2002, and continues to follow-up with Dr. Constant until 2007 for chronic Lyme disease. During this follow-up period the patient reported slurred speech, memory loss, fatigue and headaches. She is disabled and out of work, and Dr. Continues to adhere to chronic Lyme disease, because of a lack of any other explanation for her profound symptoms.

There is no record of any Lyme testing done under the care of Dr. until **10/2007**, nine years after her ongoing diagnosis of chronic Lyme disease, and this test was in fact negative.

In 1/2008, **ten years after** the first MRI reported abnormal demyelinating findings, a second MRI was done. This revealed periventricular white-matter disease, and raised the possibilities of Lyme/multiple sclerosis/vasculitis (inflammation of blood vessels). Ms. G is seen by a neurologist who performs a lumbar puncture, the results of which reveal a **negative Lyme PCR test**, yet positive oligoclonal band proteins which was consistent with the diagnosis of **Multiple Sclerosis**.

## EVALUATION OF THE PERFORMANCE OF D. C. M.D. M.D.

1. Dr. Care exhibited severe deviations from the standard of care of Name Grant from the initial evaluation until her ultimate diagnosis of multiple sclerosis. This encompasses a ten year period, where Dr. Care adhered to a diagnosis of "Neuro-Rheumatologic Lyme Disease". There was never a consideration of alternative diagnoses as raised by radiologic evidence on an MRI in 1998 and subsequent abnormal SPECT scan, and by failure of any meaningful response to over three (3) years of ongoing, inappropriate antibiotic treatment.



3. Dr. (during the ten years she was under his care while he prescribed an aggressive antibiotic treatment regimen for an infectious disease that was never proven. This is a clear deviation from the standard of care for any treating physician.

### 6. CASE OF A R

I have reviewed all the medical records provided regarding the care of A R by Dr. Decree Care and other treating physicians.

### **Medical Summary**

A was a 41 year old woman who reported an insect bite without a rash, fever or other symptoms in 1995. She sought care from her PMD, an neurologist and rheumatologist for various joint complaints, and two Lyme antibody tests were negative.

Her first visit with Dr. Carrier was 1/28/97. No neurologic or musculo-skeletal examination was performed. Dr. Carrier noted possible Lyme disease, or "false negative" Lyme disease and began treatment with amoxicillin, without any antibody testing done.

Within two months' time, the patient had doxycycline added to her treatment and plans were made to initiate intravenous ceftriaxone therapy. No physical exam was done.

Intravenous therapy and doxycycline continued for four (4) more months during which time the patient developed sun-exposure sensitivity/toxicity attributed to the doxycycline, and diarrhea. Daily intravenous therapy was switched to weekly intramuscular penicillin, which continued for fourteen (14) additional months. She then is switched back to intravenous treatment for another four and one-half months until 3/99.

In 3/99, the patient is admitted to a psychiatric facility for narcotic detoxification. After she is released, Dr. Calling initiates weekly intramuscular penicillin once again, and this continues for an additional two years, along with an oral antibiotic, azithromycin. Because of ongoing memory, concentration and fatigue complaints, Dr. C has Ms. R evaluated at Helen Hayes Hospital in 8/99 for formal neuro-psychiatric testing . The diagnosis given to Ms. Results DSM criteria included: Bipolar Disorder/ Personalilty Disorder and Narcotic Abuse. A MRI of the brain is done in 1/00, revealing few white matter abnormalities, but no spinal fluid testing is considered in the record. After being off injectable penicillin and oral azithromycin for nearly two (2) years , the patient "relapses" and penicillin injections are initiated in 11/02. Dr. Comment orders another Lyme test, which is negative, and perform his first physical examination on Ms. R after over six (6) years of the patient's care. In 2/04, Ms. R moves to Florida and over the ensuing eight (8) months, Dr. Carrier office phones in prescriptions to Florida for narcotics, including MS Contin (a morphine product) and Lortab (hydrocodone). In addition, many prescriptions are sent to the patient by Federal Express. Not until 10/04, does a prescriber in the office discuss with Dr. Common an apparent excessive usage of narcotics based upon the number of prescriptions requested and transmitted to the patient. EVALUATION OF THE PERFORMANCE OF D IN THE CARE OF A care of A R R R a patient with multiple negative Lyme tests, who is treated for nearly five (5) years of antibiotics despite side-effects, and with prolonged narcotics, contains multiple

severe deviations from the standards of care for Lyme disease and

psychiatric/addiction illness.

#### These severe deviations include:

- A lack of appropriate physical examinations by the prescribing physician. The first time Dr. Communications the patient is after she has been treated for six (6) years in his practice for a purported infectious disease. Never is a formal neurologic or joint exam done, despite Dr. Communications of neurologic and arthritic Lyme disease.
- The ongoing prescribing of narcotics, both under his direct care without any examination for source of pain, and via telephone and express mail while the patient is no longer under his direct care are clear deviations from physician prescribing expectations.
- The pattern of prescribing of narcotics to an individual who has a proven, recent history of, not only narcotic addiction and detoxification, but in addition the DSM diagnoses of Bipolar and Personality Disorders. The lack of active surveillance of narcotic usage and recognition of excessive requests for prescriptions by a narcotic addict, while out-of-state, and not under Dr.

# SUMMARY OF THE PERFORMANCE OF D. C.

As a board certified internist and infectious disease specialitst, I have provided detailed conclusions as to the performance of Carrier, M.D. as it pertains to the care of eight (8) patients in his medical practice in Mt. km., N.Y. Each of these patients were diagnosed with, and treated for Lyme disease despite the fact that every one of the patients lacked any documented clinical or serologic evidence for this infectious disease.

Never was a differential diagnosis considered in any of these patients who presented with a variety of subjective complaints. During the prolonged, unwarranted antibiotic treatment courses there was a consistent lack of any meaningful physical examination by the physician, or his assistants.

The duration and choice of antibiotic agents for the treatment of Lyme disease can be debated, but this would only be pertinent when there is an established Lyme diagnosis – a fact missing in each of these cases. To subject all of these individual patients to years of antibiotics, in cases with diagnoses as benign as chronic venous stasis of an extremity, and as crippling as multiple sclerosis, is not only beyond the treatment frontier of any infectious disorder, but clearly resulted in patient harm. Months of intramuscular injections, antibiotic-related diarrhea and rashes were all avoidable consequences of Dr. Communicessary prolonged treatment regimens.

The misrepresentation of the findings of a study in a medical journal in order to support ongoing unwarranted therapy, and to seek health and disability insurance benefits for a patient that does not meet the clinical and treatment criteria cited in the referenced literature, is a clear departure from the standard of behavior of a licensed physician.

The lack of adequate controls in prescribing narcotics, notably to a patient with recognized addiction and psychiatric illness, is a severe departure from the standards of prescribing and care expected of a licensed physician.

A consistent and unwavering pattern of clinical practice is apparent in the review of all patient records. Regardless of a patient's symptom complex, the findings on the rare cursory physical exam, and results of serologic testing, none of which are consistent with Lyme disease, each and every patient is given an exclusive diagnosis of Lyme disease, and initiated on prolonged antibiotic at the time of their first encounter with Dr. Compattern of 100% prevalence of a single diagnosis in any medical practice, even that of a specialist treating a single disease entity, does not pass any degree of medical credibility.

In closing, I think it is appropriate to consider the following practical clinical vignette as it pertains to the pattern of diagnosis and care provided by Dr. Carrow regarding Lyme disease and recognize how dangerous and unacceptable this would be:

A patient presents with symptoms of fatigue, musculo-skeletal pain, poor sleep patterns, and problems with concentration. No abnormalities are found on a limited physical exam. The physician considers only chronic hepatitis C as an exclusive diagnosis, but liver function tests are normal and antibodies (serologic test) for hepatitis C is negative. Nonetheless, the patient is told he/she is infected with hepatitis C, and the patient is then subjected to antiviral therapy, with all of its' inherent side effects, years beyond all recommended guidelines.

In reality, the above clinical scenario would never be conceived of, or accepted by the medical community.